THE EVALUATION OF CHILD LIFE AS A SAFER ALTERNATIVE TO PHARMACOLOGICAL BEHAVIOR MANAGEMENT FOR CHILDREN WITH OBJECTIVE DENTAL FEAR

A Thesis

by

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ABSTRACT

The purpose of this pilot study was to evaluate dental child-life therapy as a safe alternative to pharmacological behavior management techniques in school-age dental patients with past negative dental experiences. Seventeen fearful, uncooperative children (ages 5-11 years) with prior negative dental experiences were randomly assigned to experimental (Child Life) or control (sedation) groups. Children in both groups underwent two consecutive invasive dental restorative appointments provided by the same blinded dentist. The experimental group received three sessions of child-life therapy prior to receiving dental restorative treatment. The control group did not receive child-life interventions but were treated using meperidine and promethazine oral conscious sedation. The appointments were videotaped, and then analyzed by three calibrated, blinded examiners. Behavior was rated at specific standardized segments of treatment including seating in the chair, local anesthetic administration, rubber dam placement, and timed components of restorative care using the Modified Houpt Scale and the Frankl Score. Ratings were compared between control and experimental groups after each procedure and between first and second appointments. There was no significant difference between behaviors at all time points between visit one and visit two for the control group ($p > 0.317$). Similarly, there was no significant difference between behaviors at all time points between visit one and visit two for the experimental group ($p > 0.102$). Additionally, there was no significant difference between the consensus Frankl score by the video reviewers and the operator. ($p=0.24$ control group;

p=0.137 experimental group). There was no significant difference in behavior between control visit one and experimental visit one (p >0.328). The results suggest that oral conscious sedation remains an effective choice for patients with objective dental fear. Child life therapy is also an effective choice for patients with objective fear given the lack of difference in behaviors between treatment groups for the first visit. Child life therapy has substantivity as demonstrated by similar behavior scores between the first and second visit.

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CHAPTER I

INTRODUCTION AND LITERATURE REVIEW

Childhood experiences, in relation to interactions with others and their environment, play a crucial role in the development and well-being of a child. Sometimes these experiences are unpleasant for a child simply because of preconceived ideas or negative thoughts (subjective fear) and sometimes it arises out of experiencing physical or emotional pain first hand (objective fear). [1,2,3] Fear of bike riding due to a prior fall, fear of public speaking due to previous embarrassment, being bullied and anxiety while in the presence of healthcare providers due to previous invasive procedures such as immunizations are all examples of unpleasant experiences that may cause development of objective fear. Most of these fears that develop early in life tend to be engrained and are fears that typically carry on into adolescence and adulthood unless a child develops coping mechanisms.[1]

In order to allay preconceived fears of the unknown ("what will happen next?"), pediatric dentistry has developed numerous non-pharmacological behavior modification techniques such as "Tell-Show-Do", "flooding", guided imagery, and contingency escape, in addition to the pharmacological behavior modification techniques: nitrous oxide (N_2O), oral conscious sedation (OS), and general anesthesia (GA).[4,5]

Dentists attempt to modify behavior to build the ideal patient: one who cooperates, sits passively still and most importantly has a pleasant dental experience.

Overtly dental phobic children, who have previously experienced a difficult dental procedure (objective fear) arrive with a different, rather problematic personality and temperament than those who suffer from perceived fear.[1] For these children, conventional behavior modification techniques frequently fail, and pharmacological behavior modification techniques like OS or GA become necessary.[4,5]

OS in the dental office or GA in the operating room can provide benefits for the patient and the dental team. Extensive treatment needs, severe anxiety, uncooperative age-appropriate behavior, limited cognitive functioning, physical disability or medical conditions can all be addressed via such advanced behavior guidance modalities.[6] OS and GA also allow the practitioner and the dental team to schedule and perform treatment more efficiently. [7] Furthermore, OS and GA allow pediatric dentists to address one of the most urgent concerns, access to care. [4,5,6] OS and GA allow pediatric dentists to not only minimize the number of treatment appointments but also reduce the overall cost for dental treatment. Unfortunately, there are not enough general dentists qualified to provide such treatment modalities for children with severe dental treatment needs. Also, there are not enough dentists that participate in state funded programs such as Medicaid/SCHIP.[7]

Lin et al., performed a study to identify factors that explain variation in the U.S. for preventive dental care access.[7] Their study reveals that the number of dentists serving a population (dentist to population ratio) in the U.S. is not influenced by the demand for dental care but rather the number of people in a community's ability to pay for dental services. [7] Parts of the country with a higher prevalence of people in the lower

socioeconomic status therefore tend have dentist shortages.[7] Also, they came to the conclusion that the dentist to population ratio cannot serve as a good indicator to determine access to care for a population due to low dentist participation with Medicaid/SCHIP or other state funded programs.[7]

Although such behavior guidance modalities may sound as the ideal solution to provide dental treatment for children, regardless of individual obstacles or problems that may be present, both OS and GA pose potential risks to children. [4,5,6] The benefits must seriously be assessed along with the risks of providing treatment under such conditions. In particular, mortality and serious morbidity arising from severe respiratory complications have been reported with oral conscious sedation in young children.[5,6,8,9,10,11,12] Also, OS and GA pose emotional and financial stress on the parents and require appropriately trained professionals.[13] A few studies of complications, risks and fatal outcomes associated with oral sedation and general anesthesia are as follows:

Lee, et al in 2013, summarized deaths of pediatric patients reported in media due to dental anesthesia.[8] It was concluded that most deaths occurred among 2-5 year olds (n = 21/44), in an office setting (n = 21/44) and with a general/pediatric dentist (n = 25/44) as the anesthesia provider. In this latter group, 17 of the 25 deaths were linked with a sedation anesthetic.[8]

Oral sedatives also have post-operative lingering effects such as deep sleep, asphyxiation, irritability and vomiting in children which may either continue or begin after discharge from the dental clinic.[4] Most of these events occur within the first 8 hours, but in some children, the effects can be seen up to 24 hours later.[4,9] In a study

regarding oral sedation, Ritwik, et al., investigated post-sedation adverse events with the administration of midazolam or meperdine & hydroxyzine in children who have undergone dental treatment.[9] Out of the 46 children in their sample, in both groups (midazolam vs meperdine & hydroxyzine) 50% of the children slept in the car on the way home.[9] Three children in the meperdine and hydroxyzine group vomited in the car. A significantly larger proportion of children in the meperdine and hydroxyzine group experienced prolonged sleep.[9] More children in the midazolam group exhibited irritability within the first 8 hours. No statistical difference was found between the two groups with respect to incidence of pain, fever, vomiting, sleeping in the car, snoring and difficulty in waking up.[9] The results also indicated that most of these adverse affects occurred within the first 8 hours, but in some children these effects were seen up to 24 hours later.[9]

Cote and Wilson reported a greater distribution of adverse events in outpatient dental settings compared to inpatient settings and a greater distribution of adverse outcomes for children less than 6 years of age.[4, 8,10] This study and other similar studies reveal that although oral sedation is considered by many practitioners to be an effective advanced behavior management tool that can be employed when basic behavior guidance techniques such as Tell-Show-Do and N_2O fail, it has some negative post-operative effects which the practitioner must carefully asses and determine whether the benefits of using an oral sedative outweigh its risks.[11]

With these such findings, a practitioner may feel more inclined to perform inpatient dental treatment under GA; however, its use poses morbidity and mortality

risks as well which must be taken into consideration.[8,10] Examples of such risks include allergy to anesthesia, respiratory complications and behavioral problems.

Death is a rare and unfortunate outcome of dental treatment under general anesthesia and is often overlooked.[8,14] Underlying medical conditions and systemic issues increase the risk of death under general anesthesia and sometimes, despite a thorough health history and physical, negative outcomes such as death have been reported.[8,14] Wochna et al., presented a case of sudden death due malignant hyperthermia during general anesthesia.[15] A 4 year old patient with a dental history of multiple caries and past negative experiences, poor behavior and cooperation at multiple office visit was treatment planned for dental treatment under general anesthesia by a practitioner.[15] Review of the patient's medical history, as reported by his parents, did not provide any grounds or suspicions for the risk of developing malignant hyperthermia and did not indicate a need for extended diagnostic management or employment of any preventive measures prior to the dental procedure.[15] During the procedure complications developed, which included cardiac rhythm disorder, increased body temperature and subsequent muscle rigidity. Despite professionally performed resuscitation and help of an emergency unit, the patient died.[15]

Aside from death, which has been well documented as the most costly risk of performing dental treatment under GA[16], a morbidity that has become a recent concern for the general public and pediatric practitioners is an increased incidence of children with neurological problems and behavior disorders due to exposure to general anesthesia at a young age .[17]

Sprung, et al., examined the association between exposure to GA and development of ADHD in children within same birth cohort.[17] The study's cohort contained 5357 children observed from birth to high school graduation. After performing a detailed analysis that took into account factors such as duration of GA, number of exposures to GA, age at the time of exposure, gestational age, sex and birth weight, the results concluded that multiple (not single) exposures to procedures requiring GA during the first 2 years of life were associated with an increased incidence of ADHD.[17]

DiMaggio, et al., performed a cohort study to determine if there was an association between early childhood exposure to GA and the occurrence of developmental and behavior disorders in patients younger than 3 years of age.[18] With adjustment for sex and history of birth-related medical complications, and clustering by sibling status, the estimated hazard ratio of developmental or behavioral disorders associated with any exposure to anesthesia when they were younger than 3 years was 1.6 (95% confidence interval [CI]: 1.4, 1.8). The risk increased from 1.1 (95% CI: 0.8, 1.4) for 1 operation to 2.9 (94% CI: 2.5, 3.1) for 2 operations and 4.0 (95% CI: 3.5, 4.5) for ≥3 operations.[18] The relative risk in a matched analysis of 138 sibling pairs was 0.9 (95% CI: 0.6, 1.4).[2] As children from lower socioeconomic statuses are more likely to have more carious lesions at an earlier age than their peers from higher classes, it is more likely that they will experience dental treatment under general anesthesia. "This study concluded that the risk of being subsequently diagnosed with developmental and behavioral disorders in children who were enrolled in a state Medicaid program and who

had surgery when they were younger than 3 years was 60% greater than that of a similar group of siblings who did not undergo surgery".[18]

Many sociologists believe that the lack of cooperative behavior by children at a dental appointment is a result of the physical demands placed on the pediatric patient.[19] These demands include: leaning back in the chair, opening his/her mouth, breathing through one's nose, keeping the mouth open, not talking, etc. The Association of Care for Children's Dental Health advocates that "a child needs to be protected from overwhelming anxiety resulting from fear of the unknown.[3,20] A child obtains some sense of control from knowing what is to come and having sufficient time to prepare.[16] Therefore, many healthcare professionals advocate for the use of therapeutic play in order to increase the patient's understanding and ability to cope with the situation.[16] Therapeutic play is considered a coping mechanism, and has been studied extensively in the healthcare field for its role in psychosocial preparation of a child prior to undergoing surgical procedures.[16] Coping mechanisms are methods via which a person learns the ability to handle the demands of a certain situation.[16,20,21] Therapeutic play allows a patient to be desensitized to a situation through the use of instrument manipulation and play procedures on anatomic dolls, stuffed animals, and even themselves.[16,20,21] A coping mechanism like therapeutic play could serve as a safer alternative to pharmacological behavior management for children who suffer from dental anxiety and fear.[20]

Child life, a specialty devoted to the idea of preparatory play, was first developed in the 1920s by a group of teachers and health care professionals as a method to ease pain, alleviate anxiety and promote healthy development of hospitalized children.[22] In

the early 1920's and 30's, child life was considered a therapeutic play program incorporated in only a few hospitals around North America.[22] It was not until the middle to late 20th century that child life became its own entity in the healthcare field.[22] In the 21st century, the specialty of child life has evolved from what began with providing emotional stability to children in the hospital setting to having a place in many non-traditional settings such as hospice programs, camps, early intervention programs, courtrooms, community programs and anywhere there is a need to protect the emotional integrity of children facing stressful situations.[22]

Child life uses play, guided imagery and verbal explanations to develop coping strategies and promote emotional stability in young patients. It has been used for decades in the medical setting and is well documented to improve health care experiences for hospitalized children.[20,22,23,24]

Child life has a profound impact on the child's imaginary environment. For instance, the child becomes the doctor performing the procedure on another patient (doll) and learns to better manage his stress through understanding and visualizing what is actually going to happen. This has been shown to help the child be more cooperative in an effective manner.[23,24]

Hospital-setting studies have demonstrated that children receiving such preparatory methods have significantly better behavior prior to undergoing the medical procedure, and following the procedure, than those who do not.[20] Child life was found to promote appropriate coping mechanisms, and reduce anxiety and fear in young children being treated under general anesthesia through play sessions that were directly related to

the respective medical procedure.[24] Results of such hospital studies, raises interest of the effectiveness of utilizing child life therapy as a means of a non-pharmacologic behavior management technique for outpatient pediatric dentistry.

The utilization of child life interventions in the pediatric dental out-patient clinic could have many positive outcomes. There is the potential to develop coping skills and more importantly, lifelong cooperative patients without imposing health risks to these patients. Additionally, with the aid of a certified child-life specialist, there is no lost "dentist" time or productivity. Unfortunately, there isn't much quantitative research or data about its application in outpatient clinical pediatric dentistry.

Therefore, the purpose of this study was to evaluate dental child-life therapy as a safe alternative to pharmacological behavior management techniques in school-age dental patients with past negative dental experiences.

CHAPTER II

EVALUATION OF CHILD LIFE FOR CHILDREN WITH OBJECTIVE DENTAL FEAR

Dental phobia/ fear for children may include an injection, the handpiece ("drill"), an extraction, the dentist or the dental operatory (environment). For many children profound dental fear arises from prior, negative dental experiences (objective fear) rather than benign imaginary or perceived fears (subjective fear).[1,2] Although dental phobia has been estimated to peak during early adolescence, studies have shown that children aged 5-11 have a high level of dental fear, which peaks around age 10.[12,16,25] It is estimated that as many as 25 million U.S. citizens refuse dental treatment because of traumatic childhood experiences.[26] Helping fearful children to cope with dental procedures via therapeutic play may even help alleviate their future dental anxiety.[20,24,25,27]

To date, most studies involving child-life therapy have focused on reducing stress and increasing cooperation through understanding for children undergoing general anesthesia in the hospital setting for invasive medical procedures.[22,27] Currently there is very little evidence on whether child life therapy has significant clinical benefits for children in the dental setting. A previous study done by Hinze et al.,[28] aimed to determine whether child life therapy could alter behavior and subjective fear in children with no history of negative dental experiences. The authors concluded that child life

therapy may be a promising alternative to oral sedation for children with subjective fear but further investigation should be conducted.[28]

The specific aim of this study was to evaluate child life therapy as an effective mechanism to promote coping skills in children with objective dental fear. It was anticipated that objective fear (fear of the unknown) would be more difficult to extinguish than subjective fear. As these children tend to be older, oral sedation may be less effective due to dose/weight limitations. Therefore, if child life therapy was indeed found to promote coping skills, the secondary aim was to evaluate if it could be an effective alternative to OS.

Materials and Methods

The Institutional Review Board (IRB) at The Texas A&M University Baylor College of Dentistry in Dallas, Texas approved this prospective randomized trail. Approval for patient recruitment and consent was obtained for the preliminary data that was collected.

Seventeen patients between the ages of 5-10 were recruited from Dallas Community Dental Clinics and Baylor College of Dentistry with a documented history of past negative behavior during an invasive dental appointment. The inclusion and exclusion criteria used to select these seventeen patients were as follows:

Criteria for Inclusion of Subjects:

- English speaking child and parent only
- Between the ages of 5-10 years old, at the time of first appointment
- History of uncooperative behavior at a previous dental examination appointment (Frankl Behavior Rating of 1-2)
- Need of at least 2 invasive restorative appointments
- No medical contraindications to routine dental care

Criteria for Exclusion of Subjects:

- Non-English speaking child – parents of the child may be non-English speaking
- Children with special health care needs – These subjects were excluded due to likelihood of some degree of developmental delay. Psychological/conduct disorders were also excluded.
- Not enough treatment needed for 2 restorative appointments
- Inability to obtain diagnostic intraoral radiographs

Methods of Investigation

Patient Sampling and Group Allocation: The operator and co-investigator reviewed the patient's past dental history and behavior at the initial appointment at BCD. Patients must have experienced a negative invasive dental appointment and should have exhibited some form of uncooperative behavior. During the initial exam, the parent was approached by either the operator or co-investigator to describe the study and to ascertain the parent's interest in joining the study. These patients were randomly

assigned via block randomization into two groups: an experimental group (E) that received child life intervention but no oral sedatives before an appointment of invasive dentistry and a control group (C) that received oral sedation only before an invasive dental appointment.

The invasive dental appointment included placement of nitrous oxide nasal hood, local anesthetic injection, rubber dam isolation and a restorative dental procedure by the principal investigator. The oral conscious sedation procedure included the use of meperidine and promethazine in combination with nitrous oxide. To maintain blindness of the principal investigator/operator, the E group receiving child life interventions also received sham nitrous oxide (100% oxygen only) inhalation. (Refer to Figure 1 to see a flow chart of the experiment design). Patients from both groups received restorative dental procedure by the principal investigator.

The experimental (E) group received three 30-minute sessions of child life given by a certified child life specialist (CLS) prior to the first dental appointment. The child life appointments were specifically designed to prepare the patient for the anticipated dental procedures based on verbal and written questions to parents concerning each child's respective fears. In each session, the CLS would pretend being the dentist treating a "patient", a stuffed animal with teeth ("McKenzie Molar"). During the course of the three sessions, the patients in the E group observed the instruments used during a dental exam (counting and checking teeth with a plastic mirror and explorer). Each patient also practiced certain aspects of an operative procedure such as seating McKenzie Molar in a dental chair, placing the nitrous hood on McKenzie Molar,

spraying air and water out of the air/water syringe, using the suctions, playing with the overhead lights, rubber dam and any of the other equipment that interested the patient. The CLS also used a visual study book (developed by the CLS), which showed pictures of the operator (PI), the assistant, as well as pictures of the dental equipment. Lastly, the CLS discussed sounds, smells, tastes and any other sensations that might occur during the appointment.

A maximum of three child life sessions was suggested based on what has been used in medicine and from unpublished data.[1] Following the third session, the child proceeded straight to the dental operatory to receive invasive dental treatment. Simultaneously, the (CLS) completed a form giving her opinion for success of the desensitization appointments and predicting the child's behavior using a 3 point scale (minimum/moderate/strong likelihood of good behavior) at the dental appointment. The CLS kept this log of her predictions for each patient and did not release this information to any of the investigators of this study until the study was completed.

Patients in both groups were exposed to a restorative dental treatment provided by a single operator. For patients in the E group, the children were told not to discuss their child life experiences with the dentist to ensure the dentist remained blinded. For patients in the E group, if the child's behavior during any part of the dental appointment prevented treatment, the appointment was terminated and the child was scheduled and treated under OS in the next appointment.

All patients in the E group whose behavior was sufficiently cooperative to complete treatment returned for a second restorative dental visit, scheduled within a

week of the first, to investigate the child life intervention's lasting effect. If this appointment failed, the patient was scheduled for treatment with OS.

For children in the C group, if the child's behavior during any component of the dental appointment prevented treatment, the appointment was terminated and the child was scheduled and treated under general anesthesia.

Following the restorative appointment, the dental operator completed a form rating the behavior of the patients denoted by a Frankl Score.

All appointments were video taped and digitized. The digitized videos were spliced into 150-second clips for time points of interest during the operative visit. The spliced clips included the following time points: 1) administration of oral sedative medication if applicable (control group) and nitrous oxide hood (both E and C group), 2) administration of the local anesthetic, 3) rubber dam placement, 4) start of treatment and 5) the end of the appointment after nitrous oxide was discontinued.

These video-clips were viewed by three blinded and calibrated investigators. The 3 raters were calibrated by watching and rating randomly assorted video clips and discussing their ratings amongst each other. This was performed to assure that all three calibrators had a clear understanding on criteria for ratings and scoring as well as for inter-rater reliability. The three calibrated investigators rated the child's behavior in each segment using the Frankl scale and Modified Houpt scale (Table 1 and Table 2). The Modified Houpt scale ratings for each segment of the operative appointment and overall Frankl Scale rating provided by the three calibrators was used to calculate means (average) for all ratings. An overall Houpt score was calculated by taking the mean of the three Houpt

scores (Body Movement, Oral resistance and Verbal) for each of the five segments of the operative treatment. This data was used to calculate a consensus Houpt mean score and consensus Frankl Scale score for each segment of the appointment.

Non-parametric statistical tests were utilized to determine differences and possible correlations in behavior ratings of the operator, calibrators and the CLS and to determine if there were differences between treatment groups.

The 3-point scale that the CLS used to assess likelihood of success in the dental operative appointment was converted to the following:

- The prediction of "minimum" was correlated to Houpt scores of 1 and 2 and a Frankl score of F1/F2
- The prediction of "moderate" was correlated to Houpt score of 3 and a Frankl score of F3
- The prediction of "strong" was correlated to Houpt score of 4 and a Frankl score of F4

These conversions and correlations were made in order to create a quantifiable method of comparing CLS predictions to that of the calibrators (Houpt and Frankl ratings) and the operator (Frankl ratings).

Results

Thirty patients were recruited who met the inclusion criteria for this study. Out of the 30 patients, 17 patients made it for both visit #1 and visit #2 in their originally assigned group. Eleven patients were assigned to the child life therapy (E group). Three

patients (E group) were unable to cope with the restorative appointment. Two of these patients successfully completed both sedation appointments but were not included in the control group analysis. One patient failed to return to complete treatment.

As mentioned above, two patients' behavior deteriorated to the point that the dental appointment was terminated and the patients were brought back to finish treatment successfully under OS. In the C group, two patients' behavior deteriorated to the point that the dental treatment had to be stopped and those patients were taken to operating room to complete dental treatment under general anesthesia.

In summary, 11 patients were included in analysis for the E group; 6 patients were included in analysis for the C group. All patients originally included in the E group were included in the analysis of the CLS predictions.

Test for significance and the effect of child life intervention was measured by comparing the overall Houpt and Frankl scores for the five segments of the operative treatment between the E group and the C group using the Mann Whitney U Independent Sample Test. There was no significant difference in Houpt and Frankl scores across all dental appointment time points between the E group and C group: Overall Houpt score p-value for first visit (CV1-EV1=0.963), overall Houpt score p-value for second visit (CV2-EV2= 0.888), overall Frankl score p-value for first visit (CV1-EV1= 0.743) and overall Frankl score p-value for second visit (CV2-EV2= 0.370) (Table 3). Analysis of individual time points revealed that the E group had slightly lower Houpt scores for 3 out of the 5 time points for the first visit. Seating in the chair/administration of N2O (EV1= 3.8 vs CV1= 3.91), application of rubber dam (EV1= 3.77 vs CV1= 3.83) and

start of operative treatment (EV1= 3.86 vs CV2= 3.92). Figure 2. For the second visit the E group had lower Houpt scores for 2 out of the 5 time points: application of rubber dam: (EV2= 3.86 vs CV2= 3.9) and start of operative treatment (EV2= 3.8 vs CV2= 3.92) Figure 3. There was no correlation or patterns in behavior ratings for time points between visits for both groups and there was no significant difference in behavior between both groups.

Comparisons were also made between the two visits for the E group (EV1-EV2). This comparison was made to study the substantivity (lasting effects) of child life therapy. A comparison was also made between the C group (CV1-CV2) to determine if behavior remained the same, improved, or decline across sedation visits. Significance between the two visits for each respective group was compared using the Wilcoxon Rank-Sum related samples Test. Behavior remained consistent from the first visit to second visit in both the E group (Figure 4) and C group (Figure 5). The similarity in Houpt scores between visit 1 and visit 2 for all time points for the E group are as follows: Chair/Nitrous (EV1= 3.8 vs EV2= 3.88), Injection (EV1= 3.88 vs EV2= 3.88), Rubber Dam (EV1= 3.77 vs EV2= 3.86), Op Start (EV1= 3.86 vs EV2= 3.8), Op End (EV1= 3.89 vs EV2= 3.88) (Figure 4). The similarity in Houpt scores between visit 1 and visit 2 for all time points for the C group are as follows: Chair/Nitrous (CV1= 3.91 vs CV2= 3.83), Injection (CV1= 3.83 vs CV2= 3.76), Rubber Dam (CV1= 3.83 vs CV2= 3.9), Op Start (CV1= 3.92 vs CV2= 3.92), Op End (CV1= 3.76 vs CV2= 3.8) (Figure 5). This consistency in behavior for both groups was also shown by a non-significant difference in p-values across all time points: overall Houpt p-value between

visits for E group: (EV1-EV2= 0.892), overall Frankl p-value between visits for E group: (EV1-EV2= 0.343), overall Houpt p-value between visits for C group: (CV1-CV2= 0.577) and overall Frankl p-value between visits for C group: (CV1-CV2= 0.713). Table 3.

An evaluation of difference between the Frankl scores assessed by the operator was compared to those given by the calibrated reviewers and was stratified by groups (Figures 6 and 7). The similarities in Frankl scores between the operator and calibrated reviewers (consensus) for both the E and C group are as follows: For the C group for visit 1 (Consensus Frankl= 3.09 vs Operator Frankl= 3.44) and for visit 2 (Consensus Frankl= 3.06 vs Operator Frankl= 3.22). For the E group for visit 1 (Consensus Frankl= 3.08 vs Operator Frankl= 2.88) and for visit 2 (Consensus Frankl= 3.21 vs Operator Frankl= 3.75) (Figure 7). This similarity in Frankl ratings is also shown by our p values. There was no significant difference between the operator and raters for the control group at either visit #1 (p= 0.133) or visit #2 (p= 0.665). Likewise there was no significant difference between the operator and raters for experimental group at visit #1. There was however a significant difference for visit #2 (p= 0.027) (Table 3).

Lastly, the data was used to evaluate the CLS' ability to predict the patient's behavior. This was determined by comparing the CLS converted score to Modified Houpt scores and Frankl Scale scores given by the calibrated reviewers and the Frankl Scale scores given by the operator dentist. The CLS rated each patient at each visit.

For those three patients who were recruited but unable to complete the study in the originally assigned groups, the behavior predictions versus outcomes are as follows:

One patient (HP) was given a rating of 2 by the child life therapist but received a Frankl score of 1 by the operator. The 2nd patient (NW) was given a rating of 3 by the CLS and received a Frankl score of 1 from the operator. This patient went on to receive two reasonably successful sedation appointments. The 3rd patient (JH) received a 2 rating from CLS and received a Frankl score of 2 from the operator. This patient did not return for a follow up appointment.

An analysis of variance (ANOVA) was performed to test for significance. The results reveal there was not a statistical significant difference between prediction scores of the CLS and the operator for the first visit ($n=11$; $R= 0.543$; $p= 0.084$). There was not a significant difference between prediction scores of the CLS and the operator for the second visit ($n=8$; $R= 0.655$; $p= 0.08$). For the first operative visit, the CLS was accurate 7/11 times (64%). For the second operative visit the CLS was accurate 7/8 times (88%).

Discussion

This study was aimed at determining whether child-life therapy could benefit school-aged children with objective fear of a dental appointment. If child life therapy was helpful in alleviating dental anxiety, it would serve a possible alternative to pharmacological behavior management.

The results of this randomized clinical study demonstrated that there is no significant difference in cooperative behavior between children who have undergone three child life therapy sessions (E group) and those who have not (C group-sedation). This lack of difference in cooperative behavior between the two groups is most likely due to a small sample size. A previous study performed at Texas A&M Health Science Center Baylor College of Dentistry has shown evidence of benefits of child life therapy for pediatric dental patients with subjective fear.[30] Studies conducted in the medical setting such as ones performed by Hatava, et al., and Stevenson, et al., have also shown positive outcomes allaying fear, anxiety and cooperation using preparatory play (child life therapy).[2,31] Even though significance wasn't reached, it is likely child life therapy will have some benefit in creating coping skills.

The greatest limitation with this prospective study was the difficulty in obtaining adequate number of patients to participate. Participation in this study required that parents bring their child to three child life visits prior to obtaining dental treatment. The time and compliance necessary to attend all three child life therapy sessions was a difficult commitment for many candidates (parents and patients) due to everyone's busy work and school schedules. This could possibly explain why child life therapy is more popular in the inpatient medical setting. However, typically there is one child life visit prior to surgery.

An additional factor to consider in regards to the lack of significance difference between the E group and C group behavior was the absence of the CLS during the actual dental operative appointment. In pediatric dentistry, the dental team (staff) plays a

crucial role in shaping a child's future attitude towards dentistry by providing behavioral guidance during each appointment and the successive one.[32] For the most part, they remain a constant part of the child's dental appointments and can help allay fear and anxiety which is sometimes seen with doctor-patient interactions.[32] It is possible that patients in the E group formed a bond with the CLS, and this connection weakened as patients moved to the operatory for the dental appointment. Unfortunately, presence of the CLS in the operatory would have "un-blinded" the dentist. A possible means to overcome this obstacle in future studies and in practice could be to have an audio recording of the CLS's voice via headphones (therefore the control group also would have headphones) guiding the patient through the dental appointment in a story like fashion. Implementing audiotapes, electronic tablets or television after child life therapy sessions could be a practical means of sustaining the positive effects of therapy and be a beneficial coping mechanism for patients with objective fear.

The inclusion of nitrous oxide: oxygen analgesia was another component of our design, which could have influenced behavior but was determined to be a necessity to include in our study. Nitrous oxide is often used in conjunction with sedation to potentiate the effects of sedatives. Since our patients in both groups had objective fear due to past negative dental experiences and had proven to be uncooperative, we believed it would be best to adjunct nitrous oxide with OS for the control group and the nitrous hood but with only oxygen (sham N2O) for the CL group.

Another confounding variable was the editing of the videotapes. The videos were edited in 30-second increments surrounding the feature of interest (ex: administration of

local anesthesia). Although a patient's anxiety and fear of what is to come during a procedure may arise, it sometimes soon dissipates after the child is aware of the situation and realizes he or she is not in harm. We believed that by creating 150-second clips for each patient would allow us to assess the level of cooperation and behavior for each patient. Unfortunately our design did not include operator behavior assessment during the entire course of the procedure. To overcome this design flaw it would have been ideal if the operator had recorded Houpt scores during each segment of the procedure and not just record an overall Frankl score at the end. The Frankl score can be very subjective in nature; often a practitioner's/rater's score for a child is based on the behavior at the end of the appointment. Having Houpt scores provided by the operator would have allowed for comparison to those of the calibrated video raters. This would have allowed for better assessment of behavior during the entire course of the procedure.

Determining the long lasting effects (substantivity) of CL therapy from the first dental appointment to the second dental appointment was an important objective for this study. The results showed that the E group behavior remained consistent for both dental appointments. These results are promising and justify future research into the use of child life in the dental setting. The practicality of investment in time required by the patients and parents to attend these appointments prior to getting dental work done may be questioned as child life is not a billable dental code and may not guarantee a child's cooperation or eliminate the need for pharmacological behavior management. It should be also pointed out that for the C group behavior also remained consistent thus

validating the effectiveness of using OS as a pharmacological tool for behavior management.

The positive outcomes from the use of child life in the outpatient dental setting is promising but future studies with larger sample sizes need to be performed to truly determine the long term practicality and implementation in the field of pediatric dentistry.

CHAPTER III

CONCLUSION

The following conclusions can be drawn from this research:

1. The data suggests that there was no significant difference in behavior across all time points of the operative dental appointment between the child life (E) group and oral conscious sedation group (C).
2. As there was no significant difference between the two groups; the practicality of 3 child life sessions may be questionable.
3. Implementing audiotapes, electronic tablets or television at the day of dental treatment after child life therapy sessions could be a practical means of sustaining the positive effects of therapy and could be a beneficial coping mechanism for patients with objective fear.
4. To truly determine the benefits of child life, larger, multi centered studies need to be conducted.

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APPENDIX

TABLES AND FIGURES

Table 1. Modified Houpt Behavior Rating Scale

Modified Houpt Behavior Rating Scale	
Body Movement	
1	Violent, uninterrupted movement
2	Continuous, making treatment difficult
3	Controllable, does not interfere with treatment
4	No body movement present
Head/Oral Resistance	
1	Turns head, refuses to open mouth
2	Mouth closing, must request to open
3	Choking, gagging, spitting
4	No crying present
Verbal	
1	Verbal abuse, threats
2	Verbal protest
3	Statement of discomfort
4	Occassional talking or silence
Overall	
Based on average (mean) of scores for Body Movement, Head/Oral Resistance and Verbal scores	

Table 2. Frankl Behavioral Rating Scale

Frankl Behavioral Rating Scale		
Rating	Attitude	Definition
1	DEFINITELY NEGATIVE	Refusal of treatment, crying forcefully, fearful or any other overt evidence of extreme negativism.
2	NEGATIVE	Reluctant to accept treatment, uncooperative, some evidence of negative attitude but not pronounced, i.e. / sullen, withdrawn.
3	POSITIVE	Acceptance of treatment; at times cautious, willingness to comply with the dentist, at times with reservation but patient follows the dentist's directions cooperatively.
4	DEFINITELY POSITIVE	Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

Table 3. Listing of P-Values for Statistical Tests Between Groups and Visits

Time Points	EV1-EV2	CV1-CV2	CV1-EV1	CV2-EV2
Chair/Nitrous	0.461	0.854	0.328	0.606
Injection	0.916	0.593	0.963	0.645
Rubber Dam	0.854	0.317	0.815	0.662
Op Start	0.593	0.713	0.743	0.681
Op End	0.419	0.674	0.681	0.607
Overall Houpt	0.892	0.577	0.963	0.888
Overall Frankl	0.343	0.713	0.743	0.370
Operator Frankl Rating	0.102	0.317	0.541	0.114

Legend:

EV1=Experimental Group Visit 1

EV2= Experimental Group Visit 2

CV1= Control Group Visit 1

CV2= Control Group Visit 2

Figure 1. Flow Chart of Experiment Design

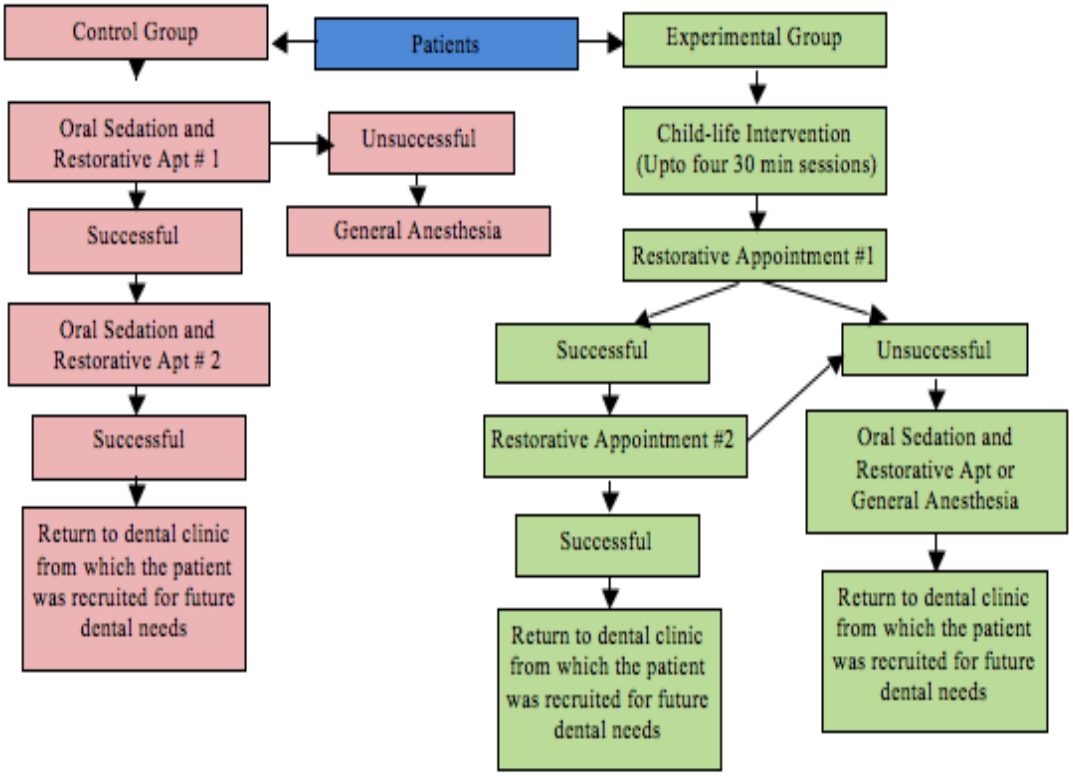

Figure 2. Comparision of Houpt Scores for the First Dental Visit

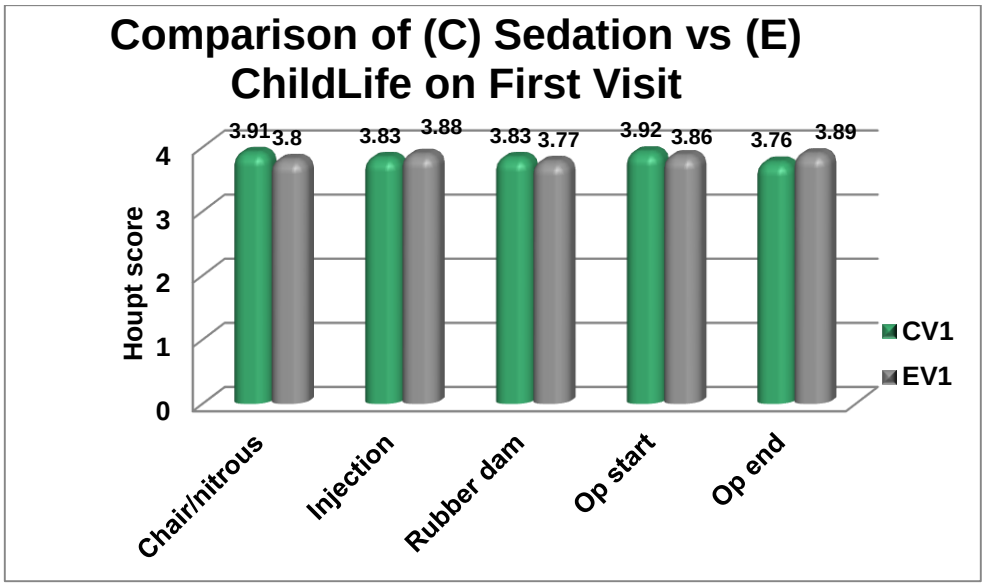

Figure 3. Comparison of Houpt Scores for the Second Dental Visit

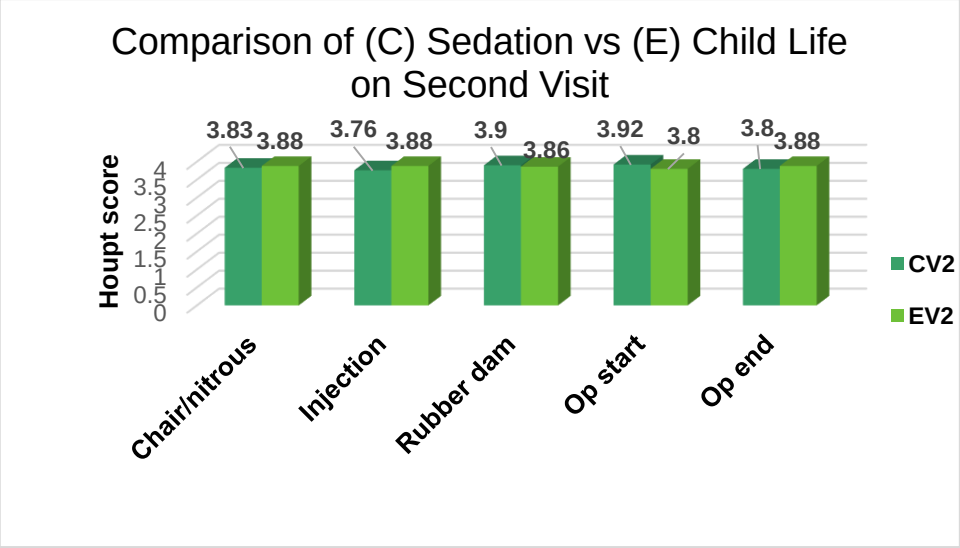

Figure 4. Substantivity of Child Life From the 1st Dental Visit to the 2nd Visit

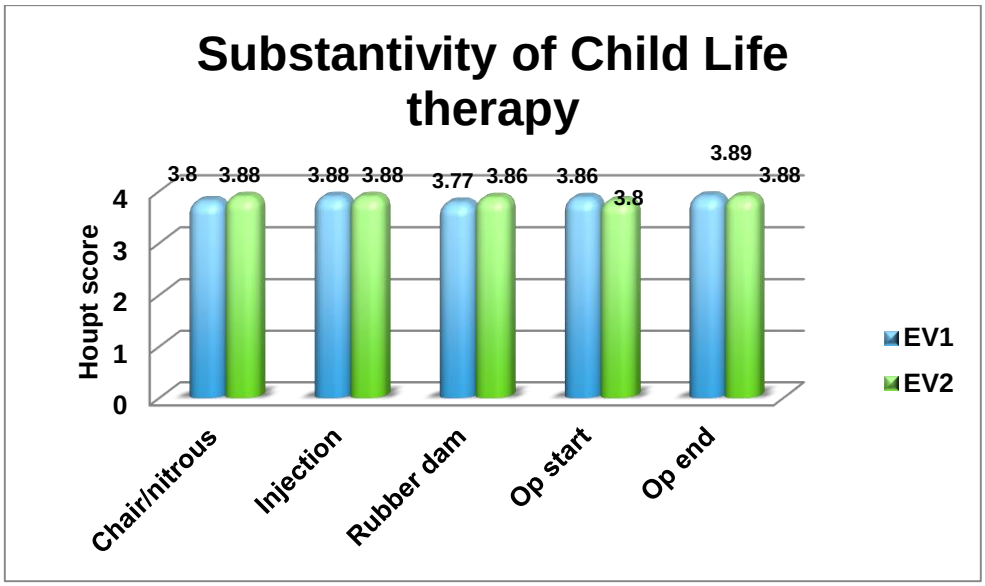

Figure 5. Substantivity of Sedation (Control)

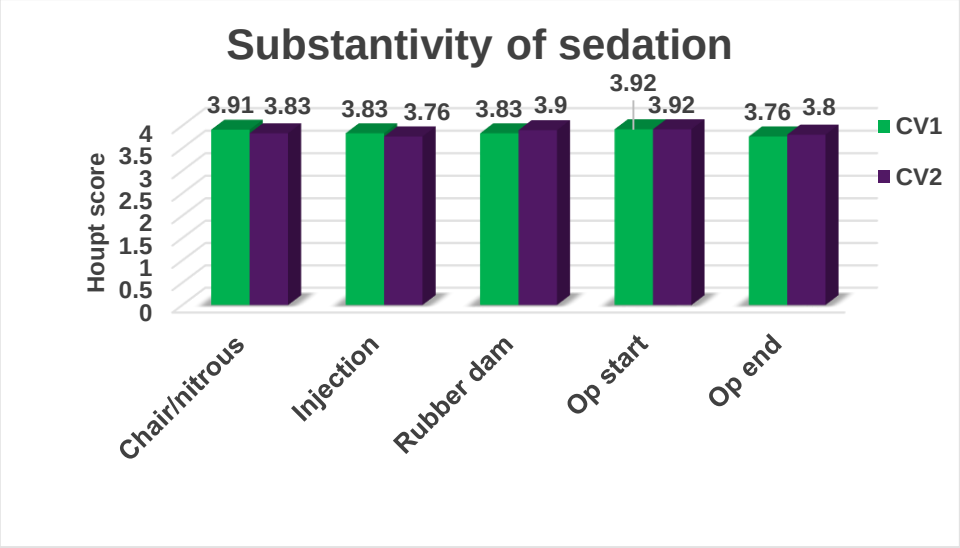

Figure 6. Frankl Scores of Operator vs. Calibrated Reviewers

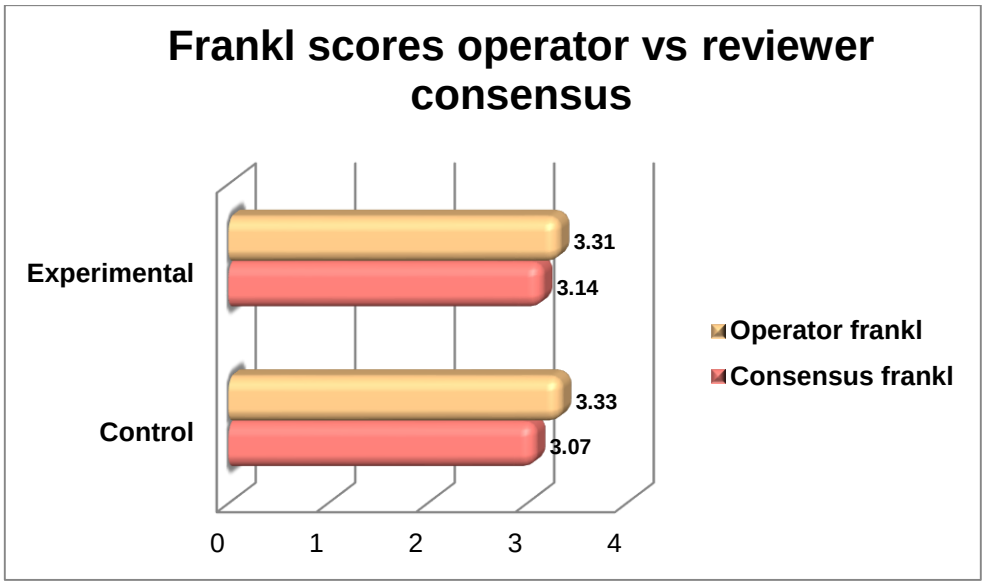

Figure 7. Difference in Frankl Scores Between Operator and Calibrated Reviewers